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| Case Number: | CM13-0034849 | | |
| Date Assigned: | 06/06/2014 | Date of Injury: | 01/21/2003 |
| Decision Date: | 07/14/2014 | UR Denial Date: | 09/24/2013 |
| Priority: | Standard | Application Received: | 10/15/2013 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Internal Medicine, has a subspecialty in Emergency Medicine and is licensed to practice in Florida. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This patient is a 58 year-old with a date of injury of 01/21/03. A progress report associated with the request for services, dated 09/11/13, identified subjective complaints of neck, low back, bilateral wrist and right shoulder pain. Objective findings included tenderness of the cervical paraspinal muscles and pain on range-of-motion. There was also tenderness of the right shoulder and bilateral carpal tunnels. Diagnoses included cervical disc disease with facet inflammation; lumbar disc disease, bilateral carpal tunnel syndrome; and right rotator cuff sprain. Treatment has included exercise and physical therapy. She utilizes a TENS unit. Medications include NSAIDS, oral and topical analgesics, and muscle relaxants. A Utilization Review determination was rendered on 09/24/13 recommending non-certification of "Flexeril 7.5 quantity 60.00 and Terocin patch quantity 20.00".

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

FLEXERIL 7.5 QUANTITY 60.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (For Pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Muscle Relaxants Page(s): 41-42; 63-66.

Decision rationale: Flexeril (cyclobenzaprine) is an antispasmodic muscle relaxant. The Medical Treatment Utilization Schedule (MTUS) states that muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The MTUS states that cyclobenzaprine (Flexeril) is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for cyclobenzaprine for chronic use. Though it is noted that cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of cyclobenzaprine to other agents is not recommended. The record does not show any indications for Flexeril beyond a short course. The patient has been on Flexeril for a prolonged period. Likewise, it has not been prescribed in the setting of an acute exacerbation of symptoms. Also, it is being used in combination with other medications which are either not recommended or has not been shown to produce an incremental benefit. Therefore, based upon the Guidelines, the record does not document the further medical necessity for Flexeril (cyclobenzaprine).

TEROCIN PATCH QUANTITY 20.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Topical Salicylates Page(s): 105; 111-113; 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain: Topical Analgesics; Salicylates Topical.

Decision rationale: Teroцин is a compounded agent consisting of menthol, capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methyl salicylate (an anti-inflammatory). The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) states that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. In this case, there is no demonstrated medical necessity for capsaicin in the compound. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. In this case, there is recommendation and therefore demonstrated medical necessity for

lidocaine as a cream in the compound. The Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documented functional improvement or recommendation for all the ingredients of the compound, and therefore the medical necessity of the compounded formulation, Terocin.